K083169

MAR 30 2009

Tayside Flow Technologies Ltd.
Traditional 510(k)

For the ePTFE SLF™ Spiral Vascular Graft

510(k) Summary

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92.

Submitter's Name:

Tayside Flow Technologies Limited

Submitter's Address:

Tayside Flow Technologies Ltd:
Unit 22, Prospect Business Centre
Technology Park, Dundee
Scotland,
DD2 1TY

Telephone +44 (0) 1382 598 532
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Establishment Registration Number:

Still to be obtained

Contact Person:

Edwin Lindsay

Telephone +44 (0) 7917134922

Date Prepared:

20th October 2008

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Traditional 510(k)
For the ePTFE SLF™ Spiral Vascular Graft

510(k) Summary

Device Classification Information:

Regulation Number	Device Name	Device Class	Product Code	Classification Panel
870.3450	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter	Class 2	DSY	Cardiovascular
870.3450	Prosthesis, Vascular Graft, Of Less Then 6mm Diameter	Class 2	DYF	Cardiovascular

Device Trade Name:

ePTFE SLF™ Spiral Vascular Graft

Device Common Name:

Vascular Graft with SLF™

Intended Use:

The ePTFE SLF™ Spiral Vascular Grafts are indicated for use as vascular prostheses.

The device is intended for use in the bypass or reconstruction of occluded or diseased peripheral arterial blood vessels above or below the knee. Graft configurations are intended for use as arterial conduits for bypass, or reconstruction of peripheral arterial blood vessels.

ONLY trained and qualified physicians and/or surgeons, under the controlled conditions of a hospital operating theatre environment are indicated for use of this device for implantation.

Summary of Substantial Equivalence:

The ePTFE SLF™ Spiral Vascular Grafts are substantially equivalent to Veryan Medical Limited SwirlGraft Graft (K051312), Bard IMPRA DistaFlo® Bypass Graft (K983861), DynaFlo™ Bypass Graft (K050049) and Vascutek PTFE Supported ePTFE Vascular Prostheses (K043552)

Device Description:

The device is a vascular graft which has a specially designed section intended to induce spiral laminar flow. The grafts are manufactured from a straight tubular expanded polytetrafluoroethylene (ePTFE) vascular graft, supplied by Vascutek Ltd.

The graft includes a helical overlay of polytetrafluoroethylene (PTFE) beading, injection moulded onto the external surface of the ePTFE tube. The function of the beading is to provide reinforcement for the tube.

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Traditional 510(k)

For the ePTFE SLF™ Spiral Vascular Graft

510(k) Summary

Technological Characteristics:

A comparative review of the ePTFE SLF™ Spiral Vascular Grafts with the predicate device found that the technological characteristics, performance and principle of operation were substantially equivalent.

Performance Data:

Bench testing and animal data demonstrated that the safety and effectiveness of the ePTFE SLF™ Spiral Vascular Grafts is equivalent to the predicate devices.

Safety and Effectiveness:

The ePTFE SLF™ Spiral Vascular Grafts utilises similar technology currently found in legally marketed predicate devices. Based on testing and comparison with the predicate device, the ePTFE SLF™ Spiral Vascular Grafts indicated no adverse indications or results. It is our determination that the ePTFE SLF™ Spiral Vascular Grafts is safe, effective and performs within its design specifications and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 0 2009

Tayside Flow Technologies LTD
c/o Tayside Flow Technologies LTD
1141 E. Hawken Way
Chandler, Arizona 85286
Attention: Mr. Edwin Lindsay

Re: K083169
Trade Name: ePTFE SLF™ Spiral Vascular Graft
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular graft prosthesis
Regulatory Class: II (two)
Product Code: DSY
Dated: February 6, 2009
Received: February 11, 2009

Dear Mr. Lindsay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vochnes

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083169

Device Name: ePTFE SLF™ Spiral Vascular Graft

Indications For Use: The ePTFE SLF™ Spiral Vascular Graft is indicated for ruse as a vascular prosthesis. It is intended for use in the bypass of reconstruction of occluded or diseased peripheral arterial blood vessels above or below the knee. Graft configurations are intended for use as arterial conduits for bypass, or reconstruction of peripheral arterial blood vessels.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices

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